

PSJ3

Exhibit 520

To: 'Ducca, Anita'[aducca@hdmanet.org]; Rebecca Kirch[RKirch@CANCER.ORG]; btwillman@aapainmanage.org[btwillman@aapainmanage.org]; Kevin Nicholson[KNicholson@NACDS.org]
Cc: Rosen, Burt[Burt.Rosen@pharma.com]
From: Cindy Steinberg
Sent: Sat 11/3/2012 7:08:28 PM
Subject: RE: Question on the Hydrocodone Combination Public Comment Docket

Anita,

Point well taken. I also sent a message to Kristina Toliver, the woman whose name was listed asking for a docket extension and a new date for the meeting so we could plan for it and haven't heard anything. I am copying this to others I know who are scheduled to speak to see if anyone has heard about FDA's plans?

Best,
Cindy

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-----Original Message-----

From: Ducca, Anita [mailto:aducca@hdmanet.org]
Sent: Friday, November 02, 2012 4:03 PM
To: 'Bob Twillman'; 'Rosen, Burt'; 'Aaron Gilson'; 'Adam Chrisney'; 'Adam Clark'; 'Alec Stone'; 'Alice Mead'; 'Alyson Lewis'; 'Amy Goldstein'; 'Andrea Best'; 'Anita Roach'; 'Ashli Douglas'; 'Barbara Gordon'; 'Bennett, Pamela (Gov't Affairs)'; 'Brian Gallagher'; 'Brian Munroe'; 'Caroline Schellhas'; 'Catherine Underwood'; 'Cathy Trzaskawka'; 'Christy Torkildson'; 'Cindy Steinberg'; 'Claudia Campbell'; 'Crystal Muilenburg'; 'Dara Mann'; 'Darrel C. Jodrey'; 'David E. Joranson'; 'David Swankin'; 'David Woodmansee'; 'Dee Delezene Browers'; 'Donna Kalauokalani'; 'Dr. Alfred Anderson'; 'Elizabeth Ernst'; 'Erensen, Jennifer'; 'Erin Morton'; 'Gail Amalia B. Katz'; 'Grant Erdel'; 'Greg Hicks'; 'Greg Thomas'; 'Jack Kalavritinos'; 'James Lavery'; 'Janet Favero Chambers'; 'Janet McUlsky'; 'Jason Grove'; 'Jeremy Scott'; 'Jerold Roschwalb'; 'Jerry Hall'; 'Cosgrove, Jewelyn'; 'Jillian Manley'; 'Jim Broatch'; 'Jody Green'; 'Jonathan Keyserling'; 'Joy Buck'; 'Judi Lund Person'; 'June Dahl PhD'; 'Justine Coffey'; 'Kaelan Hollon'; 'Karen Davis'; 'Karina Tabor'; 'Katherine Sharpe'; 'Kathleen Strauser'; 'Kathryn Tucker'; 'Kathy Sapp'; 'Kendra Calhoun'; 'Kevin L. Zacharoff'; 'Kevin Nicholson'; 'Keysha Brooks-Coley'; 'Kim Elting'; 'Freitas, Kristen'; 'Kristen Hedstrom'; 'Kristen Pulatlie'; 'Kristin Recchiuti'; 'Lenore Duensing'; 'Linda Kitlinski'; 'Lisa Pearlstein'; 'Lisa Robin'; 'Luke Poppish'; 'Maegan Martin'; 'Malcolm Monaghan'; 'Marcia Lee Taylor'; 'Marcie Bough'; 'Marsha Stanton'; 'Matt Gunderman'; 'Meredith Smith'; 'Michael Mattoon'; 'Mike Hall'; 'Mike Heffernan'; 'Myra Christopher'; 'Natacha Pires'; 'Natalie Hamm'; 'Nicole Kelly'; 'Patrick Coyne'; 'Patrick Toalson'; 'Paul Arnstein'; 'Paul Gileno'; 'Paul Scott O'Neill'; 'Paul, Ilisa Halpern'; 'Penney Cowan'; 'Peter Slone'; 'Peter VanPelt'; 'Philip Saigh Jr.'; 'Rebecca Kirch'; 'Regina Kaurich'; 'Robert Saner'; 'Robyn Kohn'; 'Ronna Hauser'; 'Rosemary Garza'; 'Westberry, Ryan'; 'Salley Welsh'; 'Scott M. Fishman'; 'Sharon Stancliff';

'Shaw, Solana'; 'Stacey Beckhardt'; 'Stephen Porada'; 'Steve LaPierre'; 'Stewart Leavitt'; 'Sue Thau'; 'Susan Rogers'; 'Tamara Sloan'; 'Theresa Connor'; 'Tiller, Kimberley'; 'Timothy Byrne'; 'Tina Tockarszewsky'; 'Tom O'Donnell'; 'Valerie Volpe'; 'Wade Delk'; 'Whitney Englander'; 'Windy Y. Carson-Smith'

Subject: Question on the Hydrocodone Combination Public Comment Docket

Dear Pain Care Forum Members,

As you know, FDA postponed the meeting on hydrocodone combination products due to the hurricane. The FR notice announcing the meeting had also indicated that they would open a public docket to provide written comments. Although not a requirement for such meetings, FDA's usual practice is to keep the docket open for about a week or so after such meetings (we appreciate this practice since it provides an opportunity to clarify any points made at the meeting that may have been confusing or in error).

This docket was set to close next Tuesday, Nov. 6 see:
<http://www.gpo.gov/fdsys/pkg/FR-2012-06-08/pdf/2012-13868.pdf>

In light of the meeting postponement, I've contacted FDA to find out if they intend to keep the docket open until after the new meeting date, or if it will still close for written comments on Nov. 6 as originally planned.

I haven't heard back from FDA, not surprising given the confusion over the hurricane. However, Nov. 6 is rapidly approaching. If anyone else has looked into this and can share any information, I'd really appreciate it.

Thank you.

Anita

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